



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Michael Lebner

Application No.: 10/625,937

Filing Date: July 24, 2003

Title: DEVICE FOR LACERATION OR INCISION CLOSURE

Art Unit: 3731

Examiner: Pantuck, B.

Docket No.: 0156-2004US01

CERTIFICATE OF MAILING

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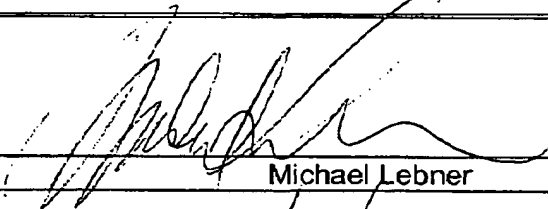
Sir:

I, Michael Lebner, declare and state as follows:

1. I am an inventor of the invention claimed in U.S. Application No. 10/625,937 filed July 24, 2003.
2. Prior to April 14, 2003, in my offices in Wellesley, Massachusetts, I conceived of the invention of Claims 1-34 of the subject patent application. This conception includes the invention of Claims 1-34 as amended in the paper filed concurrently herewith.

Documentary evidence that conception occurred before April 14, 2003 is provided in the attached Exhibit A. Exhibit A is a true copy of a six page document entitled "ClozeX Wound Closure Device Prototype Specification". This document was sent to a manufacturer on January 10, 2003. As can be clearly seen in Diagram 1, page 1, the area surrounding the cutout (see arrow) is adhesive-free. Adhesive is shown by cross-hatching on the surrounding portions of the wound closure device. Additionally, on page 3 of Exhibit A, third paragraph, the description confirms that the cutout area is adhesive free. I have many prototypes produced in the prior to April 14, 2003, which are free of adhesive in the bridging area. Prior to April 14, 2003, at least hundreds of wound closure devices, meeting the limitations of Claims 1-34 as amended in the paper filed concurrently herewith, were produced at my request according to my Specification.

3. The dates and other confidential information have been redacted in the above-referenced Exhibits.
4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature	
Name	Michael Lebner
Date	8/19/05

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ClozeX® Wound Closure Device Prototype Specifications

Introduction:

The ClozeX® wound closure design is made with adhesive backed films and removable liners on the adhesive parts. Each device is made with two separate film components that are interlaced.

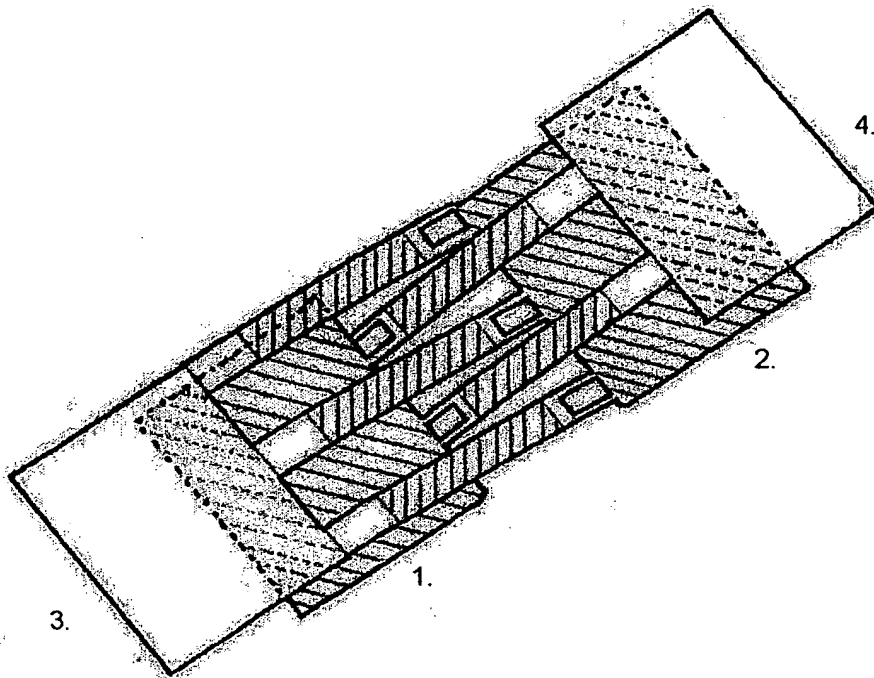
Each component contains two ends numbered 1 & 4, and 2 & 3 (see diagram 1 below). The ends are joined by interlaced filaments. Each initial end 1 & 2 is adhesively backed and adheres to the patient's skin next to the wound edge.

The other pulling ends 3 & 4 are not adhesively backed, (but may be adhesively backed in other variations).

There are strap-like filaments joining ends 1 & 4, and 2 & 3. These filaments have:

1. Cutouts at the wound edge minimize the coverage over the wound
2. Perforations that allow the pulling ends 3 & 4 to be removed
3. Adhesive strategically placed between the cutout and the perforations

Diagram 1

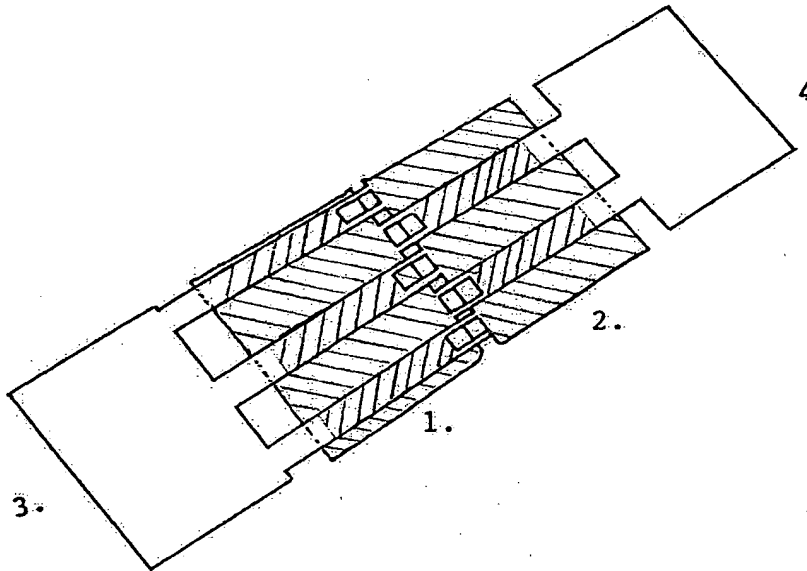


ClozeX® Device Application

1. The initial ends 1 & 2 are adhesive backed. Protective tapes are removed, and the initial ends 1 & 2 are applied on each side of the wound (See Diagram 1)

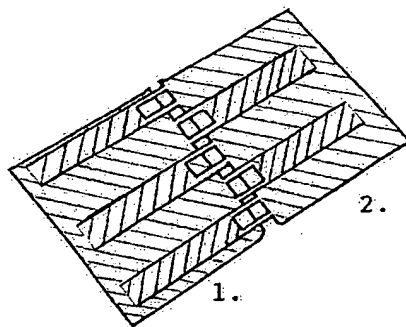
2. The strap-like filaments have adhesive strategically placed on their lower surface between the cutout area and the perforated line. After the protective tapes are removed from the lower surface of the filaments, the pulling ends 3 & 4 are used to pull (via the joining filaments) the initial ends 1 & 2. When the wound is closed satisfactorily, the filaments are lowered and anchored via the adhesive surfaces onto the inside ends 1 & 2. (See Diagram 2, below.)

Diagram 2



- 3 After the device is secured, the pulling ends 3, and 4 are discarded along with the filament ends. (See Diagram 3 below.) This is achieved by tearing each filament along the perforated line.

Diagram 3



ClozeX® Device Materials

The Film:

The current film is a **polyolefin** satisfying the following property requirements. It should be substantially inelastic (to avoid movement of the wound) and clear (to allow visibility of the skin area beneath the device). A thickness of about 3.0 mil and should have sufficient flexibility to contour to the curved areas of the body. An ideal film would have virtually no memory so as to contour to the applied surface. The **polyolefin** film is clear, flexible, and non rigid. Polyester films had a tendency to catch on the edges and proved too rigid.

The Adhesive:

The adhesive(s) is medical grade, preferably FDA approved, and used in medical devices for attachment to the skin. It should be waterproof, hypoallergenic and must **hold the device to the skin for 7-10 days** (most important feature). The adhesive for attaching the filaments to the initial ends should also have the same adherence attributes and can be the same.

Adhesive on **the initial ends 1 & 2** that apply to the skin should cover from edge to edge. The adjacent filament cutouts immediately over the wound edges should not have any adhesive on them. The filament adhesive beyond the cutout area should cover the width of the filament from the cutout area to perforated edge.

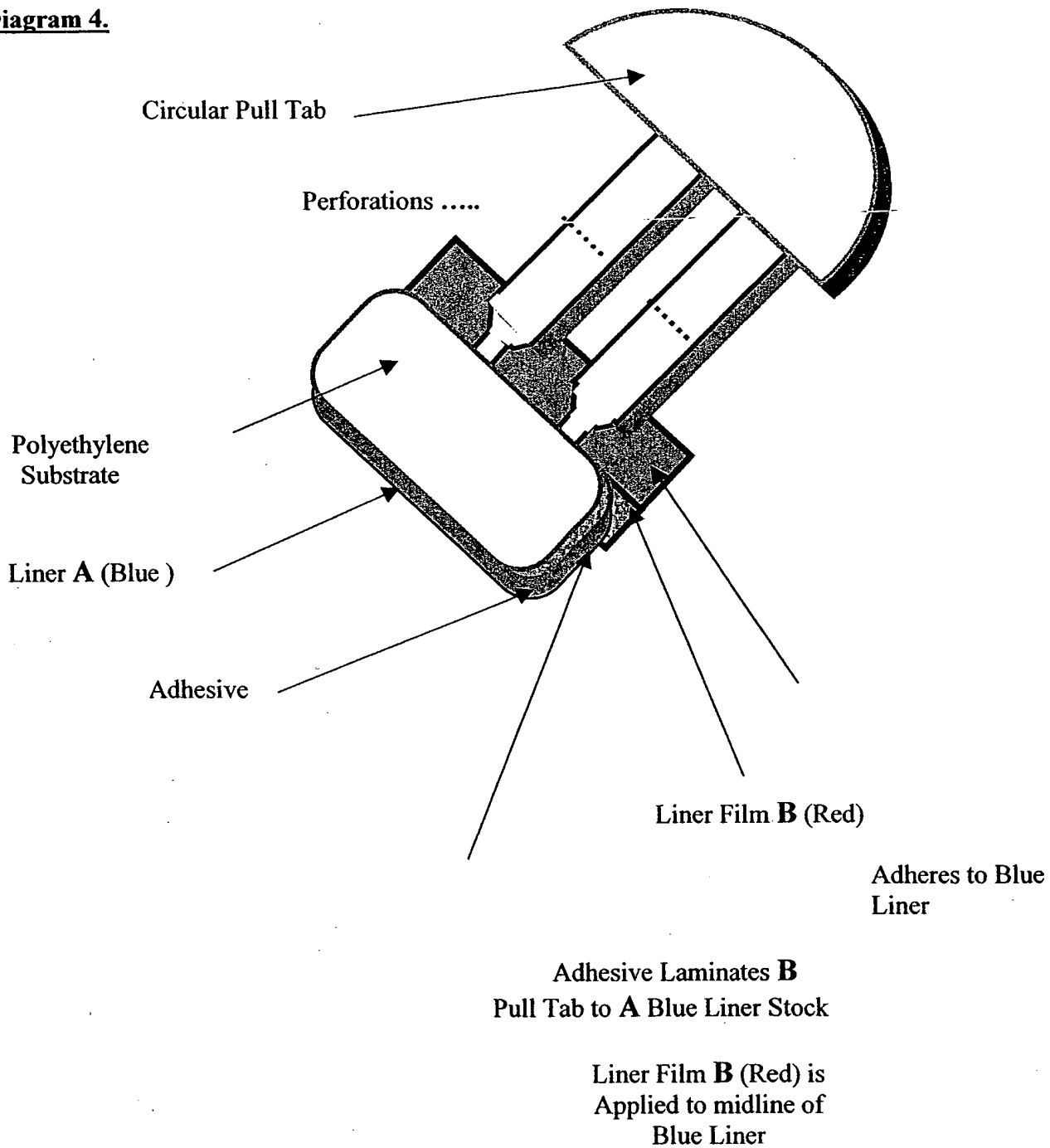
Adhesive strength should hold moist skin immediately. If maximum adhesive strength occurs after a curing period, this period should be about 10 minutes. The device should be removable right after application if an adjustment is necessary.

The Protective Liners:

The protective liners for the initial ends 1 & 2 have two films. The first film A is a thin film liner that covers 1 & 2 throughout but has a "break" feature at the center line parallel to the wound edge. A second thicker film B extends over the fine liner from the centerline extending 3/8" beyond the wound edge (under the cutout areas adjacent to 1 & 2).

During application the thicker film B is pulled back to the break exposing half of the adhesive along the wound (front) edge. Film B is then folded back under the device and lies flat extending out from the back edge. The device edge is then applied to the skin along the wound edge the extending edge of B. After application to the skin the extending edge of B is then pulled out from the back withdrawing the remaining portion of liner A. This exposes the remaining adhesive that adheres to the skin. (See Diagram 4. below.)

Diagram 4.



The protective liners for the filaments are also one part on each side. Each of these protective liners should cover the adhesive areas and extend up each filament to an area beneath the pulling ends (3 & 4) and are monolithic with their common end that is identically shaped to the pulling ends 3 & 4.

The filament Perforations or die cuts:

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Once the device is closed, the pulling end and a small portion of the attached filament must be removed. The perforation should separate easily when pulled at an angle. There should not be any residual edges/parts after removal of the pulling elements 3 & 4 that could compromise the stability of the closure.

Alignment Indicators:

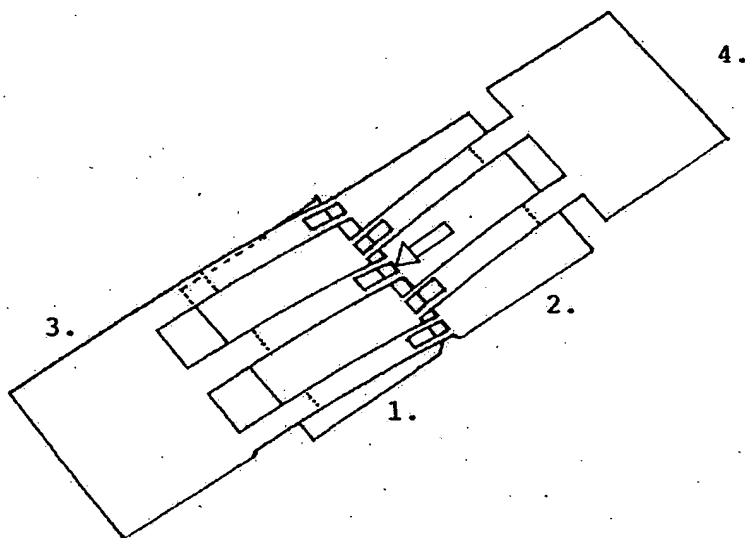
The purpose of the alignment indicators is to help place the initial ends 1 & 2 along the wound edge.

Application of Alignment Indicators is as follows. Prior to applying the ClozeX®, the laceration is gently closed manually, and at the approximate wound center, a small line/dot is drawn using a surgical pencil marking both sides of the wound. Then, these marks are used as a guide for applying the initial ends of the ClozeX® device. I.E. the indicators on the initial ends are aligned over these guide marks as each initial end is applied to the side of the laceration.

The criteria for the alignment indicators are as follows:

- A line or preferably an arrow (see diagram 5 below) at the center of the wound edge on both initial ends is suitable for now – we may want a more purposeful graphic/logo incorporated later,
- The line/arrow should be easy to see, but fine and not blocking the view to the skin underneath,
- These should be printed, but for prototypes may be drawn.

Diagram 5.



Note: The outside corners of 1 & 2 should be rounded.

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Other Requirements

The finished devices are mounted on a slightly adhesive card stock to maintain orientation when being delivered to the sterile field and to facilitate placement in a pouch suitable for sterilizing.